REMARKS

Claims 1-9 were pending in the present application. Claims 5-9 are withdrawn from consideration. By this amendment, claims 1-4 have been amended, and new claims 10 and 11 have been added. This application now includes claims 1-11.

Claims 1-4 were objected to in view of perceived formalities. Applicants have amended claims 1-4, and believe that the grounds for objection have been overcome. Accordingly, it is respectfully requested that the objection to claims 1-4 be withdrawn.

Claims 1-4 were rejected under 35 U.S.C. §112, second paragraph, as being indefinite, in that the meets and bounds of the claims are unclear. Applicants have amended claims 1-4, and believe that the grounds for rejection under 35 U.S.C. §112, second paragraph, have been overcome. Accordingly, it is respectfully requested that the rejection of claims 1-4 under 35 U.S.C. §112, second paragraph, be withdrawn.

Claims 1-4 were rejected under 35 U.S.C. 103(a) as being unpatentable over Ouchi (US 6,514,215 B1). Reconsideration is respectfully requested.

Claim 1, as amended, recites, "A biopsy apparatus, comprising: a coaxial cannula configured for insertion in tissue with the aid of a mandrel, the coaxial cannula having a proximal end and an interior wall; a biopsy needle unit configured for insertion into the coaxial cannula after the mandrel is removed from the coaxial cannula, the biopsy needle unit having an exterior wall, an interior space, and a longitudinally movable specimen separating device; and a sealing element positioned on the proximal end of the coaxial cannula, the sealing element being configured to enclose an intermediate space between the interior wall of the coaxial cannula and the exterior wall of the biopsy needle unit, wherein the sealing element is configured to provide an air outlet of the intermediate space when the biopsy

needle unit is inserted into the coaxial cannula and is configured to prevent air from entering the intermediate space after the needle unit has been positioned and a vacuum has been created in the interior space of the biopsy needle."

In rejecting claims 1-4, the Examiner relies on Ouchi Figs. 1-7 and column 5, line 40-column 6, line 30. Ouchi discloses at column 5, lines 41-45 in relation to Fig. 1, "a cannula or outer sheath 120 being pushed to the predetermined foremost position (see under A) or pulled toward the operator (see under B)." (Emphasis added). As shown in Ouchi Figs. 4-7, a needle shaft 110 and outer sheath 120 are inserted as a unit into tissue. Importantly, as shown in Ouchi Fig. 1, the foremost position A or the rearmost position B are along a portion of needle shaft 110 having a constant diameter (see Fig. 1 in relation to Fig. 3). While needle shaft 110 includes an aspiration channel 113 (in communication with aspiration device 150) along the length of needle shaft 110, no portion of aspiration channel 113 lies between foremost position A or the rearmost position B (see Ouchi, Fig. 1).

Ouchi also discloses a seal 138, and more particularly, an O-ring seal 138, located between needle shaft 110 and outer sheath 120, at a location that travels only between the foremost position A or the rearmost position B. As such, the seal arrangement disclosed by Ouchi is configured to constantly maintain the seal as between the outer sheath 120 and the needle shaft 110 (configured as a unit) within the range between the foremost position (A) and the rearward position (B) during insertion of the unit into tissue (see Ouchi Figs. 4-7). Accordingly, Ouchi does not disclose, teach or suggest a configuration that provides an air outlet of the intermediate space between the interior wall of the coaxial cannula and the exterior wall of the biopsy needle unit when the biopsy needle unit is inserted into the coaxial

cannula after the coaxial cannula is inserted into tissue and after the mandrel has been removed from the coaxial cannula, as more fully recited in claim 1.

Accordingly, claim 1 is believed allowable in its present form.

Claim 2, as amended, recites, "The biopsy apparatus of claim 1, wherein the sealing element is an elastic member defining a sealing lip and having an interior diameter, the sealing element being pushed over the proximal end of the coaxial cannula, the interior diameter being dimensioned to leave open a gap between the sealing lip of the sealing element and the biopsy needle unit, and the elasticity of the sealing element is such that, given an underpressure in the intermediate space between the exterior wall of the biopsy needle unit and the interior wall of the coaxial cannula, the sealing lip of the sealing element at the gap comes into contact with the biopsy needle unit to form a seal against the biopsy needle unit."

Claim 2, as amended, depends from claim 1, and thus is believed allowable for the reasons set forth above with respect to claim 1.

In addition, and in contrast to claim 2, Ouchi discloses a seal 138 in the form of an O-ring located in the interior bore of outer sheath 120 in annular channels. Thus, Ouchi, does not disclose, teach or suggest any arrangement of a sealing element pushed over the coaxial cannula, the sealing member having a sealing lip, with a gap between the sealing lip of the sealing element and the biopsy needle unit, and wherein the elasticity of the sealing element is such that, given an underpressure in the intermediate space between the exterior wall of the biopsy needle unit and the interior wall of the coaxial cannula, the sealing lip of the sealing element at the gap comes into contact with the biopsy needle unit to form a seal against the biopsy needle unit.

Accordingly, claim 2 is believed allowable in its own right.

Claim 3, as amended, recites, "The biopsy apparatus of claim 1, further comprising: the coaxial cannula having a cap with a proximal end and a proximal surface, and having a counterpiece on a proximal end of the cap; and a guide roller having a distal surface, and a stopper provided on the distal surface of the guide roller, the stopper being provided with sealing members, the stopper being inserted into the counterpiece on the proximal end of the cap of the coaxial cannula such that the intermediate space is closed prior to placing the distal surface of the guide roller on the proximal surface of the cap of the coaxial cannula."

Claim 3, as amended, depends from claim 1, and thus is believed allowable for the reasons set forth above with respect to claim 1.

In addition, and in contrast to claim 3, Ouchi discloses an arrangement wherein outer sheath 120 is slidably received over needle shaft 110 with an O-ring seal 138 located between needle shaft 110 and outer sheath 120, and with the O-ring seal 138 traveling between the foremost position A and the rearmost position B. Ouchi also discloses a seal 138, and more particularly, an O-ring seal 138, located between needle shaft 110 and outer sheath 120. As such, Ouchi does not disclose, teach or suggest the cap counterpiece/guide roller stopper arrangement, as recited in claim 3, wherein the stopper is inserted into the counterpiece on the proximal end of the cap of the coaxial cannula such that the intermediate space is closed prior to placing the distal surface of the guide roller on the proximal surface of the cap of the coaxial cannula.

Accordingly, claim 3 is believed allowable in its present form.

Claim 4, as amended, recites, "The biopsy apparatus of claim 1, further comprising: the coaxial cannula having a cap with a proximal end and a proximal surface, and having a counterpiece on a proximal end of the cap; a guide roller having a distal surface, and a first

stopper provided on the distal surface of the guide roller, the first stopper being provided with sealing members; and an intermediate piece having a proximal side and a distal side, the intermediate piece being positioned between the distal surface of the guide roller and the proximal surface of the cap, the intermediate piece having on the proximal side a countercoupling part with an interior bore into which the sealing members of the first stopper of the guide roller is inserted and on the distal side the intermediate piece has a second stopper with at least one second sealing member, the second stopper being inserted into counterpiece of the cap of the coaxial cannula."

Claim 4, as amended, depends from claim 1, and thus is believed allowable for the reasons set forth above with respect to claim 1.

In addition, and in contrast to claim 4, Ouchi does not disclose, teach or suggest the cap counterpiece/guide roller, first stopper/intermediate piece arrangement, as recited in claim 4, wherein the intermediate piece has on the proximal side a countercoupling part with an interior bore into which the sealing elements of the first stopper of the guide roller is inserted, and on the distal side the intermediate piece has a second stopper with at least one second sealing member, the second stopper being inserted into the counterpiece of the cap of the coaxial cannula.

Accordingly, claim 4 is believed allowable in its own right.

Thus, for at least the reasons set forth above, it is respectfully submitted that claims 1-4 as amended are patentable under 35 U.S.C. 103(a) over Ouchi.

In view of the clarifications provided by the amendments of claims 1-4, it is respectfully requested that claims 5-9 be reconsidered for examination.

Claims 10 depends from claim 1, and thus is believed patentable for the reasons set forth above with respect to claim 1. In addition, each of claims 10 and 11 further and patentably define the invention over Ouchi, and thus are believed patentable in their own right.

For the foregoing reasons, Applicants submit that the pending claims are definite and do particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Moreover, Applicants submit that the cited reference does not disclose, teach or suggest the subject matter of the pending claims. The pending claims are therefore in condition for allowance, and Applicants respectfully request withdrawal of all objections and rejections, and allowance of the claims.

In the event Applicants have overlooked the need for an extension of time, an additional extension of time, payment of fee, or additional payment of fee, Applicants hereby conditionally petition therefor and authorize that any charges be made to Deposit Account No. 20-0095, TAYLOR & AUST, P.C.

Should any question concerning any of the foregoing arise, the Examiner is invited to telephone the undersigned at (317) 894-0801.

Respectfully submitted,
/Ronald K. Aust, Reg. No. 36735/
Ronald K. Aust
Registration No. 36,735
Attorney for Applicants

RKA/ts

TAYLOR & AUST, P.C.
12029 E. Washington Street
Indianapolis, IN 46229
Telephone: 317-894-0801
Facsimile: 317-894-0803

Electronically Filed: May 1, 2009